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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,667	05/11/2007	Erik de Vries	I - 2003.010 US	2304

31846 7590 05/28/2008

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PATENT DEPARTMENT
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EXAMINER	
OGUNBIYI, OLUWATOSIN A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,667	DE VRIES ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-14 and 16-25* is/are pending in the application.

4a) Of the above claim(s) *14 and 17-20* is/are withdrawn from consideration.

5)☒ Claim(s) *1,4 and 7-10* is/are allowed.

6)☒ Claim(s) *11-13,16 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 3/26/08 has been entered into the record. Claims 2-3,5-6 and 15 have been cancelled. Claims 1,4,7-14, and 16-25 are pending. Claims 1,4,7,8-13,16 and 21-25 are under examination.

Specification

The objection to the specification and abstract is withdrawn. The amendment to the specification to remove embedded hyperlink and the abstract to remove legal phraseology is acknowledged.

Rejections Withdrawn

The rejection of claims 1,4,7-13 and 21-25 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment to claim 1.

The rejection of claim 16 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial and credible utility or a well established utility is withdrawn in view of the amendment to the claim.

The rejection of claim 16 under 35 U.S.C. 112, first paragraph, specifically, since the claimed invention is not supported by either a specific and substantial and credible utility or a well established utility is withdrawn in view of the amendment to the claim.

The rejection of claims 1,4 and 7-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment to the claims.

The rejection of claims 1, 4, 7-13, 16, 21-25 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment to the claims.

Rejections Maintained

The rejection of claims 11-13, 16 and 21-25 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons made of record in the office action mailed 12/26/07. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a vaccine comprising SEQ ID NO:2 or immunogenic fragments and also a prophylactic or therapeutic treatment of a disease or its clinical signs caused by a Babesia bovis comprising administering a vaccine comprising a protein comprising SEQ ID NO:2 or immunogenic fragments thereof or a vaccine comprising a nucleic acid comprising a nucleic acid which encodes SEQ ID NO:2 or which encodes immunogenic fragments of SEQ ID NO:2.

Applicants argue that the *in vitro* assay disclosed in the specification showing that antisera raised against 6 peptides derived from SEQ ID NO:2 inhibit invasion of erythrocytes by *Babesia bovis (B. bovis)* (fig. 5 and 6, p.30, 35-36, p. 39) provides for how SEQ ID NO;2 or its immunogenic fragments will behave *in vivo* in animals. Applicants also argue that a new *in vitro* model that mimics as closely as possible the natural invasion mechanisms of *B. bovis* (exhibit A, Franseen et al Microbes and Infection 5:365-372 (2003)) and that this serves as a reliable model for biological activity or response *in vivo* in animals. Applicants refer to MPEP section 2164.02 and that an *in vitro* model accepted for evaluating *in vivo* behavior is available (exhibit A) thus challenge data in an animal model is not required where a model that demonstrates efficacy is accepted.

All of Applicants arguments have been fully considered but are not found persuasive.

Applicants arguments as to a new *in vitro model* that mimics as closely as possible the natural invasion mechanisms of *B. bovis* is not commensurate in scope with the claims. The *in vitro* inhibition assay provided in the specification and the new *in vitro* model that mimics the natural invasion of *B. bovis* does not provide for a vaccine model for *B. bovis*. Exhibit A is drawn to a study characterizing the invasion of erythrocytes by *B. bovis*. Exhibit A does not provide for the efficacy of the instant SEQ ID NO:2 or the efficacy of a nucleic acid that encodes SEQ ID NO:2 as a vaccine. Exhibit A and the erythrocyte invasion assay in the specification does not provide any information about the protective efficacy of the claimed products (protein or DNA) *in vivo* i.e. to prevent or treat disease or clinical signs caused by *B. bovis* or to protect against infection or the protective efficacy as a vaccine. Exhibit A does not provide for an in vivo animal model of vaccine protection against *B. bovis*.

There is no challenge data in the specification of any animal model of *B. bovis* that provides evidence for a vaccine or prophylaxis or treatment of disease by *B. bovis*.

It is well recognized in the vaccine art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, S.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". While the specification demonstrates that SEQ ID NO:2 and fragments thereof are immunogenic and antisera to these interfere with erythrocyte invasion by *B. bovis*, the specification does not correlate this data with prevention of disease caused by *B. bovis* or treatment of disease or clinical signs caused by *B. bovis*. The specification does not teach the quantity and duration of the antibody response to SEQ ID NO: 2 or fragments thereof *in vivo* and how this relates to prevention or treatment of disease caused by *B. bovis* infection.

The specification does not immunize any animal with SEQ ID NO:2 immunogenic fragments or nucleic acid constructs or host cells comprising a nucleic acid sequence that encodes SEQ ID NO:2 or immunogenic fragments of SEQ ID NO: 2. Even though these protein and fragments are immunogenic this does not translate into protective efficacy. The *Babesia bovis* vaccine art at the time the instant invention was made teaches that attempts being made to develop subunit vaccines have been slow (De Vos et al. Ann N Y Acad Sci 2000; 916:540-5, cited previously). Further serologically immunodominant antigens are usually not protective

(WC Brown et al. Parasitol Today. 1999 Jul;15(7):275-81, p. 278 column 1 last paragraph, MC Jenkins, Veterinary Parasitology 101 (2001): 291-310 p. 300 first paragraph, cited previously). Preliminary results suggest that vaccines based on single antigens do not confer an adequate level or duration of protection, and it is likely that a vaccine containing several antigens will be needed to induce adequate protection (De Vos et al. Ann N Y Acad Sci 2000; 916:540-545 p. 544). Franssen et al (exhibit A) also teaches that the inherent immunogenicity of a parasite molecule does not correlate with its protective capacity (p. 371 column 2 last sentence of first complete paragraph). Thus, based on the teachings of the Babesia vaccine art, it is unpredictable that the instantly claimed proteins or nucleic acid constructs can elicit a protective immune response commensurate with the scope of the claims i.e. a vaccine/prophylactic or therapeutic treatment for disease or clinical signs caused *B. bovis*.

Status of Claims

Claims 11-13, 16 and 21-25 are rejected. Claims 1,4 and 7-10 are free of art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645